# SetPoint Medical Reports New Data Demonstrating its Bioelectronic Medicine Effectively Reduces Crohn's Disease Activity

*Results Delivered in Oral Presentation at Digestive Disease Week 2019*

**Valencia, CA – May 20, 2019 –** SetPoint Medical, a clinical-stage bioelectronic medicine company developing therapy for chronic autoimmune diseases, today announced new positive clinical data from a proof-of-concept study evaluating its bioelectronic medicine approach for the treatment of Crohn's Disease, a debilitating condition caused by inflammation of the gastrointestinal tract.

The results, presented in an oral presentation during Digestive Disease Week (DDW) 2019 in San Diego, CA, show clinically meaningful reductions in disease activity in the majority of patients, along with improvements in mucosal healing as documented by endoscopy. New biomarker data revealed reductions in several key inflammatory mediators and improvement in disease-associated autonomic imbalance. Quality of life assessments demonstrated improvements in patient-reported outcomes in a significant proportion of highly drug refractory Crohn's Disease patients.

The single-arm, open-label study conducted across five centers in Europe treated 16 biologic–refractory patients with active Crohn's Disease. All 16 patients were implanted with a vagus nerve stimulating (VNS) device to deliver proprietary digital doses of electricity designed to activate the innate inflammatory reflex to produce a systemic anti-inflammatory effect and help regulate the immune system. Patients were separated into two cohorts: the first were washed off their biologic drugs and received only VNS monotherapy and the second cohort continued their biologic drugs, to which they had inadequate clinical response, in addition to adjunctive VNS therapy.

At 16 weeks, enhanced clinical response, with CDAI score improvement of 100 or more points, was observed in eight of 16 patients, with four patients achieving CDAI remission (CDAI below 150). On average, levels of serum biomarkers associated with inflammation, such as IL-1β, TNF-α, TNF-β, and IL-12p70, at 16 weeks were reduced compared to baseline, while an anti-inflammatory cytokine, IL-10, increased from baseline indicating pharmacodynamic activation of the inflammatory reflex. Patient-reported outcomes indicated a significant improvement in quality of life for seven of the 16 patients who had previously been refractory to biologic therapy. Over the course of the study, ten patients had an improvement in their autonomic balance, the ratio of sympathetic to vagal tone as measured by heart rate variability, with the shift towards values typically observed in the healthy population.

"This study demonstrated meaningful improvements in the clinical scores of disease activity for patients with biologic refactory Crohn's Disease," said David Chernoff, MD, Chief Medical Officer of SetPoint Medical. "These clinical results accompanied with the new biomarker confirmation are important as they demonstrate the underlying pathways that are modulated by activating the inflammatory reflex via vagus nerve stimulation. By significantly reducing pro-inflammatory biomarkers these results further validate our unique bioelectronic approach for treatment of inflammation-mediated autoimmune diseases. Patients with Crohn's Disease and other related inflammatory disorders who have failed biologic therapy need new therapeutic

options. We are committed to delivering novel alternative approaches for the treatment of patients with Crohn's Disease."

Results of the study were presented in an oral presentation, titled, "Vagus Nerve Stimulation Reduces Disease Activity and Modulates Serum and Autonomic Biomarkers In Biologic-Refractory Crohn's Disease," by Geert D'Haens, MD, PhD, Head of the Academic Medical Centre (AMC)-Inflammatory Bowel Disease Unit at the University of Amsterdam, Netherlands on Sunday, May 19th during DDW 2019. The positive interim safety and efficacy data from the proof-of-concept study were initially presented at DDW 2018.[i]

**About SetPoint Medical**

SetPoint Medical is a privately held clinical-stage bioelectronic medicine company dedicated to treating patients with chronic autoimmune diseases. SetPoint Medical's bioelectronic medicine platform is intended to offer patients and providers a treatment alternative for rheumatoid arthritis, inflammatory bowel disease and other chronic autoimmune conditions with potentially less risk and cost than drug therapy. The company is developing a novel bioelectronic medicine platform that stimulates the vagus nerve to activate the inflammatory reflex to produce a systemic immune-restorative effect. Current investors in the company include New Enterprise Associates (NEA), Morgenthaler Ventures, Topspin Partners, SightLine Partners, GlaxoSmithKline's Action Potential Venture Capital and Boston Scientific as well as an additional undisclosed strategic investor (leading medical device company). For more information, visit www.setpointmedical.com.

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**References**

[i] SetPoint Medical. DDW 2018. https://setpointmedical.com/setpoint-medical-presents-positive-data-from-its-clinical-study-of-bioelectronic-medicine-for-treatment-of-crohns-disease/